

EXAMINER'S AMENDMENT AND REASONS for ALLOWANCE

1. The response and amendment filed 07 June 2011 to the Office Action with Final Rejection mailed 07 April 2011 is acknowledged and entered.

Claims Status

2. According to the response cited *supra*, following is the status of the Claims:
- ⌚ Claims 16 and 25 have currently been cancelled;
 - ⌚ Claims 1, 11-12, 18, 21, 23-24, 26 and 29 have currently been amended.; and
 - ⌚ Claims 1-15, 17-24 and 26-30 are currently pending and are examined on merits.

Withdrawn Rejections

3. Considering the amendments and remarks filed 07 June 2011, all objections and rejections in the Office Action with Final Rejection mailed 07 April 2011 are hereby withdrawn.

Examiner's Amendment

4. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on 29 June 2011 with Mr. B.J. Sadoff, Applicants' Representative.

Amendments to the Claims

In the Claims:

Please amend the following claims in the instant application.

1. (Currently Amended) A tubular tissue growth guide comprising [L,];

an inner core comprising a biopolymer matrix seeded with cells;

an outer sheath surrounding said inner core[L,];

said inner core being tethered to said outer sheath only at opposing ends of said guide;

said seeded cells providing e mechanical tension in said core between the tethered opposing ends.

2. (Currently Amended) A tubular guide according to claim 1, wherein the mechanical tension in said core causes alignment of the cells.

3. (Currently Amended) A tubular guide according to claim 1, wherein the mechanical tension in said core causes alignment of the fibres of said biopolymer matrix.

4. (Previously Presented) A tubular guide according to claim 1, wherein the biopolymer matrix is a collagen matrix.

5. (Currently Amended) A tubular guide according to claim 1 adapted for use as an implant in the repair of damaged tissue.

6. (Currently Amended) A tubular guide according to claim 5, wherein the outer sheath comprises one or more entry ports for entry of regenerating tissue.

7. (Currently Amended) A tubular guide according to claim 5 adapted for the regeneration of nerves.

8. (Currently Amended) A tubular guide according to claim 7, wherein the outer sheath comprises an entry port for entry of regenerating nerve and an exit port for exit of a regenerating nerve.

9. (Currently Amended) A tubular guide according to claim 8 comprising one or more fixings for fixing in place the entry point adjacent to the proximal end of a damaged nerve and the exit point at the distal end of a damaged nerve.

10. (Currently Amended) A tubular guide according to claim 5, wherein the mechanical tension in the core imparts traction on regenerating tissue in the guide

11. (Currently Amended) A tubular guide according to claim 1, wherein said seeded cells comprise one or more of Schwann cells, neural fibroblasts, fibroblasts, tenocytes, astrocytes, osteoblasts, myoblasts, melanocytes, smooth muscle cells, secretory or gland vessel cells, epithelial cells and endothelial cells.

12. (Currently Amended) A tubular guide according to claim 11, wherein said cells comprise Schwann cells and fibroblasts.

13. (Currently Amended) A tubular guide according to claim 1, wherein said outer sheath is biosorbable.

14. (Currently Amended) A tubular guide according to claim 1, wherein said outer sheath is non-porous.

15. (Currently Amended) A tubular guide according to claim 1, wherein said outer sheath is selected from the group consisting of-silicone, phosphate glass, polylactone, polyglycone, polycapryolactone, hyaluronan or derivatives thereof,

collagen, fibrin, fibronectin, cellulose, chitosan, and starch.

Claim 16. (Canceled)

17. (Currently Amended) A tubular guide according to claim 1, wherein said outer sheath is shaped to cooperatively engage the inner core at the tethered ends to prevent co-axial movement of the core relative to the said outer sheath.

18. (Currently Amended) A tubular guide according to claim 1, wherein said outer sheath comprises one or more openings which cooperatively engage the inner core at the opposing ends.

19. (Currently Amended) A tubular guide according to claim 1, wherein said openings comprise a plurality of pores.

20. (Currently Amended) A tubular guide according to claim 1, wherein said openings comprise one or more holes in the said outer sheath.

21. (Currently Amended) A tubular guide according to claim 1, wherein the said outer sheath is chemically fixed to the core at the tethered ends.

22. (Previously Presented) A guide according to claim 1 adapted for *in vitro* use as a bioreactor for the growth of tissue.

23. (Currently Amended) A method of making a guide for tissue growth comprising the:

providing an outer sheath the;

introducing cells to a liquid biopolymer matrix to produce a cell seeded matrix [,.];
introducing said cell seeded matrix to the interior of the outer sheath [,.];
causing or allowing said cell seeded matrix to set; and[.],
fixing [[the] said cell seeded matrix to [[the]] said outer sheath to tether said cell seeded matrix to only the opposite ends of said outer sheath.

24. (Currently Amended) A method according to claim 23, wherein [[the]] said outer sheath cooperatively engages [[the]] said cell seeded matrix at the opposing ends of said outer sheath said ~~engagement~~ tethering preventing co-axial movement of the core relative to [[the]] said outer sheath.

Claim 25. (Canceled)

26. (Currently Amended) A method of facilitating growth of tissues in a human or animal body comprising implanting a tubular tissue growth guide of claim 1 into a human or animal body in need of said facilitating.

27. (Currently Amended) A method according to claim 23, wherein the cells comprise fibroblasts and one or more cells of said tissue.

28. (Currently Amended) A method according to claim 23, wherein the tissue cells comprise fibroblasts and one or more stem cells or progenitor cells of cells of said tissue.

29. (Currently Amended) A method of claim 26, further comprising linking ends of [[the]] said tissue growth guide to broken ends of a damaged tissue in the human or animal[.],; and[.];

allowing said tissue to regenerate through said tubular tissue growth guide.

30. (Currently Amended) A method according to claim 29, wherein the damaged tissue is a nerve.

Examiner's Reasons for Allowance

5. The closest applicable art to instantly claimed invention are:

- ✓ US Patent 5,948,654 issued 07 Sept 1999 to Tranquillo et al.
Tranquillo et al. teach tissue-equivalent and biopolymer tubes that include collagen fibrills providing mechanical properties to said materials. Said tissue equivalent preparation comprises collagen with mammalian cells integrated in said structures, but the orientation of said structure is provided by

magnetic fields, not because the biopolymers interspersed mammalian cells are anchored to the tube at opposite ends.
- ✓ US Patent 6,461,629 B1 issued 08 October 2002 to Tranquillo et al.
Tranquillo et al. teach a structure comprising collagen fibrils interspersed with mammalian cells and said structure circumferentially oriented with the tubular body by a magnetic field. In Tranquillo et al's teachings, the tube does not anchor the collagen fibril comprising mammalian cell structure at opposite ends of said tube.

The claimed invention, however, describes tubular tissue growth guide comprising: an inner core comprising a biopolymer matrix seeded with cells, an outer sheath surrounding said inner core and said inner core being tethered to said outer sheath only at opposing ends of said

guide. Therefore, the claimed invention is neither anticipated by, nor is obvious over the cited prior art referred to *supra*.

6. Any comments considered necessary by Applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee.

Conclusion

7. Claims 1-15, 17-24 and 26-30 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue X. Liu can be reached at (571)-272-5539 Monday through Friday 9:00 A.M. to 4:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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